

100-1524

3/21/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 21 2014

Ms. Susan MacIntosh
Regulatory Consultant for Syngenta Crop Protection, LLC
MacIntosh & Associates, Inc.
1203 Hartford Avenue
Saint Paul, MN 55116-1622

Re: Syngenta Crop Protection, LLC; SOYACYST™ ST Plus
EPA Registration No. 100-1524
Minor Label ("Fast Track") Amendment
Submissions Dated 11/01/2013, 03/12/2014, and 03/13/2014
Decision No. 484850.

Dear Ms. MacIntosh:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Adjustment of the format, sequence, and/or content of some of the label information (e.g., warranty statement and EPA Registration Number) to reflect a recent transfer of the registration to Syngenta Crop Protection, LLC.
- 2) Correction of minor typographical errors.
- 3) Addition of the following statement to the 3rd bullet of the User Safety Recommendations box: "If gloves are worn, wash the outside of gloves before removing."
- 4) Addition of claims and application instructions related to pre-plant (on-farm) and commercial treatment of sugarbeet seed for protection against sugarbeet cyst nematode (*Heterodera schachtii*).

Additionally, you have requested approval of supplemental labeling for sugarbeet seed treatment (pre-plant or on-farm and commercial) for protection against sugarbeet cyst nematode (*Heterodera schachtii*).

CONCURRENCES

YMBOL	7511P	7511P	7511P				
USERNAME	KAUSCH	Boys	Neski				
DATE	03/13/2014	3/20/14	3/21/14				

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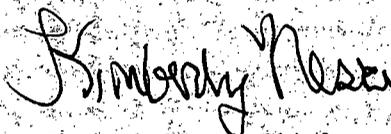
Susan MacIntosh
EPA Registration No. 100-1524

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling. Moreover, as the supplemental labeling was requested on your initiative and is based upon the enclosed stamped, accepted label, within 18 months of the date of this letter, such supplemental labeling must be integrated into the labeling affixed to or accompanying product that is distributed or sold (40 CFR § 152.130(c)).

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch of my staff by telephone (703-347-8920) or email (kausch.jeannine@epa.gov).

A stamped, accepted copy of the label is enclosed for your records.

Sincerely,



Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):

- SOYACYST™ ST Plus Stamped, Accepted Label
- A-79 Enclosure

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(Master)

SOYACYST™ ST Plus
[Alternate Brand Name: Clariva™ pn]

Nematicide

A biological seed treatment product for protection against listed nematodes on soybeans and sugarbeets

Active Ingredient:		
<i>Pasteuria nishizawae</i> – Pn1*	15.000%
Other Ingredients:	85.000%
Total:	100.000%

* Contains at least 1.0 x 10¹⁰ spores per mL or 3.8 x 10¹³ spores per gal.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary and first aid statements in booklet [on label].

EPA Reg. No. 100-1524

EPA Est. XXXX

SCP 1524-MAS 0313

Net Contents

[Batch code to be marked directly on container]

ACCEPTED

MAR 21 2014

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 100-1524**

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FIRST AID	
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call 1-800-888-8372	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

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- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards [less than 5 gallons]

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

Environmental Hazards [greater than or equal to 5 gallons]

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

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CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not use this product until you have read the entire label. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box apply only to the uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours. Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water) is:

- Waterproof gloves
- Coveralls
- Shoes plus socks

NON – AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treatment areas until seeds have dried or been packaged.

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PRODUCT INFORMATION

This product contains a biological nematicide for protection against the following nematodes:

Soybean Cyst Nematode
Sugarbeet Cyst Nematode

Heterodera glycines
Heterodera schachtii

FOR USE AS A SEED TREATMENT

Treatment of highly mechanically scarred or damaged seed, or seed known to be of low vigor and poor quality, except for the purpose of curative control of existing disease pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat a small quantity of seed using equipment similar to that planned for treating the total seed lot. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Due to seed quality, crop or variety sensitivity, and seed storage conditions beyond the control of manufacturer, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.

FOR USE AS A PRE-PLANT ON-FARM SEED TREATMENT

Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seeds beyond planting time.

To achieve improved application coverage to the seed, dilute SOYACYST™ ST Plus with water and apply directly to dry seed or mix with inoculants and/or other registered seed treatment coatings (e.g., colorants, polymers, etc.), insecticides and fungicides. Do not mix SOYACYST™ ST Plus with any product containing a label prohibition against such mixing. When tank-mixing with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both SOYACYST™ ST Plus and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates.

SOYBEAN

For protection against soybean cyst nematode, apply 0.9 to 33.8 fl. oz. of SOYACYST™ ST Plus per 100 Lbs (25 to 1000 mL per 45.4 kg) of soybean seed.

SUGARBEET

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For protection against sugarbeet cyst nematode, apply 0.034 to 1.35 fl. oz. (1.0 to 40 mL) of SOYACYST™ ST Plus product per unit (100,000 seeds) of sugarbeet seed.

FOR USE AS A COMMERCIAL SEED TREATMENT

To achieve improved application coverage to the seed, dilute SOYACYST™ ST Plus with water and apply directly to dry seed or mix with inoculants and/or other registered seed treatment coatings (e.g., colorants, polymers, etc.), insecticides and fungicides. Do not mix SOYACYST™ ST Plus with any product containing a label prohibition against such mixing. When tank-mixing with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both SOYACYST™ ST Plus and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates.

NOTE: This product does not contain dye. All seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for humans or feed for animals.

The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information: "This seed has been treated with *Pasteuria nishizawae* - Pn1. Do not use for food, feed or oil purposes."

SOYBEAN

For protection against soybean cyst nematode, apply 0.9 to 33.8 fl. oz. of SOYACYST™ ST Plus per 100 Lbs (25 to 1000 mL per 45.4 kg) of soybean seed.

SUGARBEET

For protection against sugarbeet cyst nematode, apply 0.034 to 1.35 fl. oz. (1.0 to 40 mL) of SOYACYST™ ST Plus product per unit (100,000 seeds) of sugarbeet seed.

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store between a range of 32°F to 100°F. Reclose container of unused portions of SOYACYST™ ST Plus.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling [less than or equal to 5 gallons]

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

Container Handling [greater than 5 gallons]

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!

SOYACYST™ [Clariva™], the ALLIANCE FRAME, the SYNGENTA Logo, and the PURPOSE ICON are Trademarks of a Syngenta Group Company

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For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, LLC
P. O. Box 18300 •
Greensboro, North Carolina 27419-8300

SCP 1524-MAS 0313

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(Non-detachable Container Label)

SOYACYST™ ST Plus

[Alternate Brand Name: Clariva™ pn]

Nematicide

A biological seed treatment product for protection against listed nematodes on soybeans and sugarbeets

Active Ingredient:

Pasteuria nishizawae – Pn1* 15.000%

Other Ingredients: 85.000%

Total: 100.000%

* Contains at least 1.0×10^{10} spores per mL or 3.8×10^{13} spores per gal.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary and first aid statements in booklet.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-1524

EPA Est. XXXX

SCP 1524-MAS 0313

Net Contents

[Batch code to be marked directly on container]

FIRST AID	
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>	
<p>HOT LINE NUMBER</p> <p>For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call 1-800-888-8372</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards [less than 5 gallons]

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

Environmental Hazards [greater than or equal to 5 gallons]

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Store between a range of 32°F to 100°F. Reclose container of unused portions of SOYACYST™ ST Plus.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling [less than or equal to 5 gallons]

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

Container Handling [greater than 5 gallons]

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!

SOYACYST™ [Clariva™] and the SYNGENTA Logo are Trademarks of a Syngenta Group Company

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Manufactured for:
Syngenta Crop Protection, LLC
P. O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1524-MAS 0313

SOYACYST ST PLUS 1524 MAS 0313 AMEND OCT2013 VERC CLEAN.docx
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SUPPLEMENTAL LABELING

Syngenta Crop Protection, LLC
P. O. Box 18300
Greensboro, North Carolina 27419-8300
SCP 1524A-S1 XXXX

SOYACYST™ ST PLUS
[Alternate Brand Name: Clariva™ pn]

Nematicide

A biological seed treatment product for protection against sugarbeet cyst nematode on sugarbeets

This supplemental labeling expires on March 15, 2017 and must not be used or distributed after this date.

Active Ingredient:	
<i>Pasteuria nishizawae</i> – Pn1*	15.000%
Other Ingredients:	85.000%
Total:	100.000%

* Contains at least 1.0 x 10¹⁰ spores per mL or 3.8 x 10¹³ spores per gal.

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 100-1524

All applicable directions, restrictions and precautions on the EPA-registered label are to be followed. Before using SOYACYST™ ST PLUS as permitted according to this Supplemental Labeling, read and follow all applicable directions, restrictions, and precautions on the EPA-registered label on or attached to the pesticide product container. This Supplemental Labeling contains revised use instructions and/or restrictions that may be different from those that appear on the container label. This Supplemental Labeling must be in the possession of the user at the time of pesticide application. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.



ACCEPTED

MAR 21 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 100-1524

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DIRECTIONS FOR USE

This product contains a biological nematicide for protection against the following nematode:

Sugarbeet Cyst Nematode

Heterodera schachtii

FOR USE AS A PRE-PLANT ON-FARM SEED TREATMENT

SUGARBEET

For protection against sugarbeet cyst nematode, apply 0.034 to 1.35 fl. oz. (1.0 to 40 mL) of SOYACYST™ ST Plus product per unit (100,000 seeds) of sugarbeet seed.

FOR USE AS A COMMERCIAL SEED TREATMENT

SUGARBEET

For protection against sugarbeet cyst nematode, apply 0.034 to 1.35 fl. oz. (1.0 to 40 mL) of SOYACYST™ ST Plus product per unit (100,000 seeds) of sugarbeet seed.

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SOYACYST ST PLUS 1524-S1 1013-dt-03-13-14